



# CLASS II MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

(disponible en français)

**1. NAME(S) OF DEVICE LICENCE(S) BEING AMENDED**

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**2. LICENCE NUMBER(S) TO BE AMENDED** (provide the **latest valid** licence number(s))

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**3. MANUFACTURER INFORMATION** (as it appears on the label)

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**4. REGULATORY CORRESPONDENT INFORMATION**     Same as Manufacturer     Other (specify below)

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**5. INVOICING INFORMATION**     Same as Manufacturer     Same as Regulatory Correspondent     Other (specify below)

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**6. QUALITY MANAGEMENT SYSTEM CERTIFICATE** (ensure that certificate is attached)

Quality Management System Certificate Number:	Name of Registrar:
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**7. ATTESTATIONS**

Specific to Part 1, Section 32(2), item (c), (d), and (e) of the <i>Medical Devices Regulations</i> relevant to the licensing of Class II medical devices, a senior official shall submit an application to the Minister that contains the following attestations as applicable ( <b>check (✓) the relevant attestations</b> ):	
<input type="checkbox"/>	I, <b>the Manufacturer</b> of this device, have objective evidence to establish that this device meets the safety and effectiveness requirements set out in the <i>Medical Devices Regulations</i> , Part 1, Sections 10 through 20 inclusive.
<input type="checkbox"/>	I, <b>the Manufacturer</b> of this device, have met all the labelling requirements set out in the <i>Medical Devices Regulations</i> , Part 1, Sections 21 through 23 inclusive.
<input type="checkbox"/>	The device IS a near patient IVDD. I, <b>the Manufacturer</b> of this device, have evidence of investigational testing of this device using human subjects representative of the intended user and under conditions similar to the intended conditions of use of the device.
<input type="checkbox"/>	The device IS NOT a near patient IVDD.



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**I, as a senior official of the manufacturer named in Item 3 of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.**

**Where a person is named in Item 4 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Bureau to direct all correspondence relating to this application to the person named in Item 4 of this application. Please ensure that all information and documents set out in Section 32 of the *Medical Devices Regulations* that are relevant to the change has been enclosed.**

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## COMPLETE ITEMS 8 & 9 ONLY IF THEY HAVE CHANGED FROM THE PREVIOUS LICENCE

### 8. PLACE OF USE

Is this device sold for home use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is this device used at a point of care, such as a pharmacy, bedside, or healthcare professional's office? ( <i>In Vitro Diagnostic Devices [IVDD] ONLY</i> )	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is this device an IVDD?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

### 9. MEDICAL DEVICES CONTAINING DRUGS

#### 9.1 Non-IVD Devices Containing Drugs

If the device contains a drug and is not an IVDD, indicate the Drug Identification Number (DIN) or the Natural Product Number (NPN) and complete the information listed below. If the drug does not have a DIN or NPN, please provide the Drug Establishment Licence (DEL) number of the company from where the drug is sourced.

Brand / Trade Name of Drug:	DIN/NPN:
Active Ingredient(s):	
Drug Manufacturer:	
DEL Number:	

#### 9.2 IVDD Test Kits containing Controlled Substances

If this device is an IVDD test kit containing a substance listed in Schedule I, II, III, or IV of the Controlled Drugs and Substances Act, complete the section below.

Is this an IVDD Test Kit containing a controlled substance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Test Kit Number (T.K. Number):		

**Please note:** The manufacturer will need to contact the Office of Controlled Substances to obtain a T.K. Number if one has not yet been issued.



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**10. REASON FOR AMENDMENT** (✓ appropriate change)

▶ A change to the classification of a device	<input type="checkbox"/>	From Class: _____ To Class: _____
▶ A change in the manufacturer's name	<input type="checkbox"/>	Ensure that item 1 is completed
▶ A change in the device name (i.e. previous device name no longer available for sale)	<input type="checkbox"/>	New device name: _____ (add attachment if more space is needed)
▶ A change to the purpose/indication of a Class II device	<input type="checkbox"/>	<p>A description of the medical conditions, purposes and uses for which the device will now be manufactured, sold or represented (Note: failure to supply an appropriate level of detail may result in an unsuccessful application)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
▶ An addition, deletion or change in device components or associated model, part or catalogue numbers	<input type="checkbox"/>	Complete below











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## LICENCE APPLICATION DISCLOSURE REQUEST

As you are aware, Health Canada is striving to add transparency to the medical device review process. One area we would like to address is the requests from interested parties regarding whether or not a licence application has been received by the Medical Devices Bureau (MDB).

The purpose of this form is to request your signed authorization - in advance - if we receive such a request, to disclose the date on which a licence application has been received by the MDB. No other information would be supplied.

Please indicate your consent by completing this form and sending it with your application for a new medical device licence, or any time after a licence has been granted.

### Disclosure Statement:

In the case where the Medical Devices Bureau (MDB) has received requests concerning the status of the new licence application, amendment application, or fax-back application for (enter device name)

from interested parties,

- this certifies that (enter the manufacturer's name) \_\_\_\_\_ has **no objection** to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB
- this certifies that (enter the manufacturer's name) \_\_\_\_\_ **objects** to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB

In accordance with the *Access to Information Act*, confidential, third party information will not be disclosed without your expressed consent.

\_\_\_\_\_  
Manufacturer's authorized signing official

Application forms should be sent to:

Device Licensing Services Division  
Medical Devices Bureau  
Therapeutic Products Directorate  
Health Canada  
2934 Baseline Road  
Address Locator: 3403A  
OTTAWA, Ontario K1A 0K9

Phone: (613) 957-7285

Fax: (613) 957-6345

E-mail: device\_licensing@hc-sc.gc.ca